FDA 510(k) Premarket Notification

CLEARED

K200968 ABC33L, ABC35L, ABC37L, ABC39L, ABC33R, ABC35R, ABC37R, ABC39R

Dec 28, 2020
262 days to decision

K200968 · Product code: **CBI** · Anesthesiology
Source: https://www.510kdatabase.net/k200968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI)
Date received	Apr 10, 2020
Decision date	Dec 28, 2020
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Insung Medical Co., Ltd.**
Location	Gangwon-Do, KR
Contact	Tae-il An
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	DongHa Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov